DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

21 CFR Ch. I

42 CFR Chs. I-V

45 CFR Subtitle A; Subtitle B, Chs. II, III, and XIII

Regulatory Agenda

AGENCY: Office of the Secretary, HHS

ACTION: Semiannual Regulatory Agenda

SUMMARY: The Regulatory Flexibility Act of 1980 and Executive Order (EO) 12866 require the semiannual issuance of an inventory of rulemaking actions under development throughout the Department with a view to offering summarized information about forthcoming regulatory actions for public review.

FOR FURTHER INFORMATION CONTACT: Jennifer M. Cannistra, Executive Secretary, Department of Health and Human Services, Washington, D.C. 20201.

SUPPLEMENTARY INFORMATION:

The information provided in the Agenda presents a forecast of the rulemaking activities that the Department of Health and Human Services (HHS) expects to undertake in the foreseeable future.

Rulemakings are grouped according to pre-rulemaking actions, proposed rules, final rules, long-term actions, and rulemaking actions completed since the spring 2011 Agenda was published.

Please note that the rulemaking abstracts included in this paper issue of the **Federal Register** relate strictly to those prospective rulemakings that are likely to have a significant economic impact on a substantial number of small entities, as required by the Regulatory Flexibility Act of 1980. Also available in this issue of the **Register** is the Department's submission to the Fiscal Year 2011 Regulatory Plan, required under Executive Order 12866.

The complete Regulatory Agenda of the Department is accessible online at www.reginfo.gov in an interactive format that offers users enhanced capabilities to obtain information from the Agenda's database. The purpose of the Agenda is to encourage more effective public participation in the regulatory process.

NAME: Jennifer M. Cannistra,
Executive Secretary to the Department

Substance Abuse and Mental Health Services Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
321	Opioid Drugs in Maintenance or Detoxification Treatment of Opiate Addiction **(Section 610 Review)**	0930–AA14

Centers for Disease Control and Prevention—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
322	Establishment of Minimum Standards for Birth Certificates	0920–AA46

Centers for Disease Control and Prevention—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
323	Control of Communicable Diseases: Foreign	0920–AA12
324	Control of Communicable Diseases: Interstate	0920–AA22

Food and Drug Administration—Prerule Stage

Sequence Number	Title	Regulation Identifier Number
325	Over-the-Counter (OTC) Drug Review—Sunscreen Products	0910–AF43
326	Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures **(Section 610 Review)**	0910–AG14
327	Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents **(Section 610 Review)**	0910–AG61
328	General Requirements for Blood, Blood Components, and Blood Derivatives; Donor Notification **(Section 610 Review)**	0910–AG62

Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
329	Electronic Submission of Data From Studies Evaluating Human Drugs and Biologics **(Reg Plan Seq No. 33)**	0910–AC52
330	Over-the-Counter (OTC) Drug Review—Internal Analgesic Products	0910–AF36
331	Over-the-Counter (OTC) Drug Review—Topical Antimicrobial Drug Products	0910–AF69
332	Import Tolerances for Residues of Unapproved New Animal Drugs in Food	0910–AF78
333	Laser Products; Amendment to Performance Standard	0910–AF87
334	Current Good Manufacturing Practice and Hazard Analysis and	0910–AG10

	Risk-Benefit Preventive Controls for Food for Animals **(Reg Plan Seq No. 34)**	
335	Over-the-Counter (OTC) Drug Review-Pediatric Dosing for Cough/Cold Products	0910–AG12
336	Electronic Distribution of Content of Labeling for Human Prescription Drug and Biological Products	0910–AG18
337	Amendment to the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals—Second Phase	0910–AG20
338	Unique Device Identification **(Reg Plan Seq No. 35)**	0910–AG31
339	Produce Safety Regulation **(Reg Plan Seq No. 36)**	0910–AG35
340	Hazard Analysis and Risk-Based Preventive Controls **(Reg Plan Seq No. 37)**	0910–AG36
341	"Tobacco Products" Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act	0910–AG38
342	Human Subject Protection; Acceptance of Data From Clinical Studies for Medical Devices	0910–AG48
343	General Hospital and Personal Use Devices: Issuance of Draft Special Controls Guidance for Infusion Pumps	0910–AG54
344	Requirements for the Testing and Reporting of Tobacco Product Constituents, Ingredients, and Additives	0910–AG59
345	Amendments to the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals—Components	0910–AG70

References in boldface appear in The Regulatory Plan in part II of this issue of the **Federal Register**.

Food and Drug Administration—Final Rule Stage

Sequence	Title	Regulation

Number		Identifier Number
346	Infant Formula: Current Good Manufacturing Practices; Quality Control Procedures; Notification Requirements; Records and Reports; and Quality Factors **(Reg Plan Seq No. 40)**	0910–AF27
347	Label Requirement for Food That Has Been Refused Admission Into the United States	0910–AF61
348	Food Labeling: Nutrition Labeling for Food Sold in Vending Machines **(Reg Plan Seq No. 43)**	0910–AG56
349	Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments **(Reg Plan Seq No. 44)**	0910–AG57

References in boldface appear in The Regulatory Plan in part II of this issue of the **Federal Register**.

Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
350	Food Labeling; Revision of the Nutrition and Supplement Facts Labels	0910–AF22
351	Over-the-Counter (OTC) Drug Review—Oral Health Care Products	0910–AF40
352	Pet Food Labeling Requirements	0910–AG09
353	Further Amendments to General Regulations of the Food and Drug Administration to Incorporate Tobacco Products	0910–AG60
354	Food Labeling: Hard Candies and Breath Mints	0910–AG82
355	Food Labeling; Serving Sizes; Reference Amounts for Candies	0910–AG83

Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
356	Over-the-Counter (OTC) Drug Review—Cough/Cold (Bronchodilator) Products	0910–AF32
357	Over-the-Counter (OTC) Drug Review—Poison Treatment Drug Products	0910–AF68
358	Cigarette Warning Label Statements	0910–AG41

Centers for Medicare & Medicaid Services—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
359	Covered Outpatient Drugs (CMS-2345-P) **(Section 610 Review)**	0938–AQ41
360	Medicare and Medicaid Electronic Health Record Incentive Program—Stage 2 (CMS-0044-P)	0938–AQ84
361	Medicare and Medicaid Programs: Reform of Hospital and Critical Access Hospital Conditions of Participation (CMS-3244-P) **(Reg Plan Seq No. 45)**	0938–AQ89
362	Proposed Changes to Hospital OPPS and CY 2013 Payment Rates; ASC Payment System and CY 2013 Payment Rates (CMS-1589-P) **(Section 610 Review) (Reg Plan Seq No. 47)**	0938–AR10
363	Revisions to Payment Policies Under the Physician Fee Schedule and Part B for CY 2013 (CMS-1590-P) **(Section 610 Review) (Reg Plan Seq No. 48)**	0938–AR11
364	Changes to the Hospital Inpatient an Long-Term Care	0938–AR12

	Prospective Payment System for FY 2013 (CMS-1588-P) **(Section 610 Review) (Reg Plan Seq No. 49)**	
365	Transparency Reports and Reporting of Physician Ownership of Investment Interests (CMS-5060-F)	0938–AR33

References in boldface appear in The Regulatory Plan in part II of this issue of the **Federal Register**.

Centers for Medicare & Medicaid Services—Completed Actions

Sequence Number	Title	Regulation Identifier Number
366	Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and FY 2012 Rates and to the Long-Term Care Hospital PPS and FY 2012 Rates (CMS-1518-F) **(Completion of a Section 610 Review)**	0938–AQ24
367	Revisions to Payment Policies Under the Physician Fee Schedule and Part B for CY 2012 (CMS-1524-FC) **(Completion of a Section 610 Review)**	0938–AQ25
368	Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2012 (CMS-1525-F) **(Completion of a Section 610 Review)**	0938–AQ26
369	Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities for FY 2012; Required Disclosures of Ownership (CMS-1351-F) **(Completion of a Section 610 Review)**	0938–AQ29
370	Home Health Prospective Payment System Refinements and Rate Update for CY 2012 (CMS-1353-F) **(Section 610 Review)**	0938–AQ30
371	Enhanced Federal Funding for Medicaid Eligibility Determination	0938–AQ53

	and Enrollment Activities (CMS-2346-F)	
372	Five Year Review of Work Relative Value Units Under the Physician Fee Schedule (CMS-1582-PN)	0938–AQ87

Department of Health and Human Services (HHS)	**Final Rule Stage**
Substance Abuse and Mental Health Services Administration (SAMHSA)	

321. OPIOID DRUGS IN MAINTENANCE OR DETOXIFICATION TREATMENT OF OPIATE ADDICTION (SECTION 610 REVIEW)

Legal Authority: 21 USC 823 (9); 42 USC 257a; 42 USC 290aa(d); 42 USC 290dd–2; 42 USC 300xx–23; 42 USC 300x–27(a); 42 USC 300y–11

Abstract: This rule would amend the Federal opioid treatment program regulations. It would modify the dispensing requirements for buprenorphine and buprenorphine combination products that are approved by the Food and Drug Administration (FDA) for opioid dependence and used in federally certified and registered opioid treatment programs.

Timetable:

Action	**Date**	**FR Cite**
NPRM	06/19/09	74 FR 29153
NPRM Comment Period End	08/18/09	
Final Action	02/00/12	

Regulatory Flexibility Analysis Required: No

Agency Contact: Nicholas Reuter, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Suite 2–1063, One Choke Cherry Road, Rockville, MD 20857

Phone: 240 276–2716

Email: nicholas.reuter@samhsa.hhs.gov

RIN: 0930–AA14

Department of Health and Human Services (HHS)	Proposed Rule Stage
Centers for Disease Control and Prevention (CDC)	

322. • ESTABLISHMENT OF MINIMUM STANDARDS FOR BIRTH CERTIFICATES

Legal Authority: 42 USC 264

Abstract: Section 7211 of the Intelligence Reform and Terrorism Prevention Act (IRTPA) mandates that HHS establish, by regulation, minimum standards to improve the security of birth certificates for use by Federal agencies for official purposes.

Timetable:

Action	Date	FR Cite
NPRM	09/00/12	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Charles Rothwell, Director, Division of Vital Statistics, Department of Health and Human Services, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 7311, M, Hyattsville, MD 20782

Phone: 301 458–4555

RIN: 0920–AA46

Department of Health and Human Services (HHS)	Long-Term Actions
Centers for Disease Control and Prevention (CDC)	

323. CONTROL OF COMMUNICABLE DISEASES: FOREIGN

Legal Authority: 42 USC 243; 42 USC 264 and 265; 42 USC 267 and 268; 42 USC 270 and 271

Abstract: The final rule focuses primarily on requirements relating to the reporting of deaths and illnesses onboard aircrafts and ships traveling from foreign countries into the United States, and the collection of

specific traveler contact information for the purpose of CDC contacting travelers in the event of an exposure to a communicable disease.

Timetable:

Action	Date	FR Cite
NPRM	11/30/05	70 FR 71892
NPRM Comment Period End	01/20/06	
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Ashley Marrone, Public Health Analyst, Department of Health and Human Services, Centers for Disease Control and Prevention, MS–E03, 1600 Clifton Road NE., Atlanta, GA 30329

Phone: 404 498–1600

Email: amarrone@cdc.gov

RIN: 0920–AA12

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324. CONTROL OF COMMUNICABLE DISEASES: INTERSTATE

Legal Authority: 28 USC 198; 28 USC 231; 25 USC 1661; 42 USC 243; 42 USC 248 and 249; 42 USC 264; 42 USC 266 to 268; 42 USC 270 to 272; 42 USC 2001

Abstract: This rule focuses primarily on requirements relating to the reporting of deaths and illnesses onboard aircrafts traveling domestically, and the collection of specific traveler contact information for the purpose of CDC contacting travelers in the event of an exposure to a communicable disease.

Timetable:

Action	Date	FR Cite
NPRM	11/30/05	70 FR 71892
NPRM Comment Period End	01/30/06	
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Ashley Marrone, Public Health Analyst, Department of Health and Human Services, Centers for Disease Control and Prevention, MS–E03, 1600 Clifton Road NE., Atlanta, GA 30329

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Email: amarrone@cdc.gov

RIN: 0920–AA22

Department of Health and Human Services (HHS)	**Prerule Stage**
Food and Drug Administration (FDA)	

325. OVER–THE–COUNTER (OTC) DRUG REVIEW—SUNSCREEN PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The first of the future actions will address the safety of sunscreen active ingredients. The second of the future actions will address active ingredients reviewed under time and extent applications. The last action addresses combination products containing sunscreen and insect repellent ingredients.

Timetable:

Action	**Date**	**FR Cite**
ANPRM (Sunscreen and Insect Repellent)	02/22/07	72 FR 7941
ANPRM Comment Period End	05/23/07	
NPRM (UVA/UVB)	08/27/07	72 FR 49070
NPRM Comment Period End	12/26/07	
Final Action (UVA/UVB)	06/17/11	76 FR 35620
NPRM (Effectiveness)	06/17/11	76 FR 35672
NPRM (Effectiveness) Comment Period End	09/15/11	

ANPRM (Dosage Forms)	06/17/11	76 FR 35669
ANPRM (Dosage Forms) Comment Period End	09/15/11	
ANPRM (Safety)	06/00/12	
NPRM (Time and Extent Applications)	08/00/12	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: David Eng, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5487, 10903 New Hampshire Avenue, Silver Spring, MD 20993

Phone: 301 796–2773

Fax: 301 796–9899

Email: david.eng@fda.hhs.gov

RIN: 0910–AF43

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326. PRESCRIPTION DRUG MARKETING ACT OF 1987; PRESCRIPTION DRUG AMENDMENTS OF 1992; POLICIES, REQUIREMENTS, AND ADMINISTRATIVE PROCEDURES (SECTION 610 REVIEW)

Legal Authority: 21 USC 331; 21 USC 333; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 381

Abstract: Pursuant to section 610 of the Regulatory Flexibility Act, FDA is currently undertaking a review of regulations promulgated under the Prescription Drug Marketing Act (PDMA) including those contained in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763). The purpose of this review is to determine whether the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763) should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statues, to minimize adverse impacts on a substantial number of small entities. FDA solicited comments on the following: (1) The continued need for the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763); (2) the nature of complaints or comments received from

the public concerning the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763); (3) the complexity of the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763); (4) the extent to which the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763) overlap, duplicate, or conflict with other Federal rules, and to the extent feasible, with State and local governmental rules, and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763).

Last year, FDA extended the completion date by one year due to the RxUSA Wholesale, Inc., v. HHS case. Since then, the case has ended and FDA proposed to withdraw section 203.50(a). Therefore, FDA will complete the review by December 2011.

Timetable:

Action	**Date**	**FR Cite**
Begin Review of Current Regulation	11/24/08	
End Review of Current Regulation	12/00/11	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Howard Muller, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 6234, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002

Phone: 301 796–3601

Fax: 301 847–8440

Email: pdma610(c)review@fda.hhs.gov

RIN: 0910–AG14

327. REQUIREMENTS FOR TESTING HUMAN BLOOD DONORS FOR EVIDENCE OF INFECTION DUE TO COMMUNICABLE DISEASE AGENTS (SECTION 610 REVIEW)

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360c and 360d; 21 USC 360h and 360i; 21 USC 371 and 372; 21 USC 374; 21 USC 381; 42 USC 216; 42 USC 262 to 264; 42 USC 263; 42 USC 263a; 42 USC 264

Abstract: FDA is undertaking a review of 21 CFR sections 610.40, 610.41, 610.42, 610.44, 640.67, 640.70, (as amended in 66 FR 31146) under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations in 21 CFR sections 610.40, 610.41, 610.42, 610.44, 640.67, 640.70 (as amended in 66 FR 31146) should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize adverse impacts on a substantial number of small entities. FDA will consider, and is soliciting comments on, the following: (1) The continued need for the rule; (2) the nature of complaints or comments received concerning the rule from the public; (3) the complexity of the rule; (4) the extent to which the rule overlaps, duplicates, or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules; and (5) the length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

Timetable:

Action	Date	FR Cite
Begin Review of Current Regulation	06/01/11	
End Review of Current Regulation	12/00/11	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Melissa Reisman, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, Suite 200N (HFM–17), 1401 Rockville Pike, Rockville, MD 20852

Phone: 301 827–6210

RIN: 0910–AG61

328. GENERAL REQUIREMENTS FOR BLOOD, BLOOD COMPONENTS, AND BLOOD DERIVATIVES; DONOR NOTIFICATION (SECTION 610 REVIEW)

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 and 352; 21 USC 355; 21 USC 360 and 360j; 21 USC 371; 21 USC 374; 42 USC 216; 42 USC 262; 42 USC 263a; 42 USC 264; . . .

Abstract: FDA is undertaking a review of 21 CFR sections 606.100(b), 606.160(b) and 630.6 (as amended in 66 FR 31165) under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations in 21 CFR sections 606.100(b), 606.160(b) and 630.6 (as amended in 66 FR 31165) should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize adverse impacts on a substantial number of small entities. FDA will consider, and is soliciting comments on, the following: (1) The continued need for the rule; (2) the nature of complaints or comments received concerning the rule from the public; (3) the complexity of the rule; (4) the extent to which the rule overlaps, duplicates, or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules; and (5) the length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

Timetable:

Action	Date	FR Cite
Begin Review	06/01/11	
End Review	12/00/11	

Regulatory Flexibility Analysis Required: No

Agency Contact: Melissa Reisman, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, Suite 200N (HFM–17), 1401 Rockville Pike, Rockville, MD 20852

Phone: 301 827–6210

RIN: 0910–AG62

Department of Health and Human Services (HHS)	Proposed Rule Stage
Food and Drug Administration (FDA)	

329. ELECTRONIC SUBMISSION OF DATA FROM STUDIES EVALUATING HUMAN DRUGS AND BIOLOGICS

Regulatory Plan: This entry is Seq. No. 33 in part II of this issue of the **Federal Register**.

RIN: 0910–AC52

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330. OVER–THE–COUNTER (OTC) DRUG REVIEW—INTERNAL ANALGESIC PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 379e

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The first action addresses acetaminophen safety. The second action addresses products marketed for children under 2 years old and weight- and age-based dosing for children's products.

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Required Warnings and Other Labeling)	12/26/06	71 FR 77314
NPRM Comment Period End	05/25/07	
Final Action (Required Warnings and Other Labeling)	04/29/09	74 FR 19385
Final Action (Correction)	06/30/09	74 FR 31177
Final Action (Technical Amendment)	11/25/09	74 FR 61512
NPRM (Acetaminophen)	06/00/12	

NPRM (Amendment) (Pediatric)	12/00/12	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Mary Chung, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993

Phone: 301 796–0260

Fax: 301 796–9899

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RIN: 0910–AF36

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331. OVER–THE–COUNTER (OTC) DRUG REVIEW—TOPICAL ANTIMICROBIAL DRUG PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The first action addresses consumer products. The second action addresses testing requirements.

Timetable:

Action	Date	FR Cite
NPRM (Healthcare)	06/17/94	59 FR 31402
Comment Period End	12/15/95	
NPRM (Consumer)	04/00/12	
NPRM (Food Handlers)	To Be	Determined
NPRM (Testing)	To Be	Determined
Final Action (Consumer)	To Be	Determined
Final Action (Testing)	To Be	Determined
Final Action (Food Handlers)	To Be	Determined

Final Action (First Aid Antiseptic)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: David Eng, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5487, 10903 New Hampshire Avenue, Silver Spring, MD 20993

Phone: 301 796–2773

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Email: david.eng@fda.hhs.gov

RIN: 0910–AF69

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332. IMPORT TOLERANCES FOR RESIDUES OF UNAPPROVED NEW ANIMAL DRUGS IN FOOD

Legal Authority: 21 USC 342; 21 USC 360b(a)(6); 21 USC 371

Abstract: The Food and Drug Administration (FDA) plans to publish a proposed rule related to the implementation of the import tolerances provision of the Animal Drug Availability Act of 1996 (ADAA). The ADAA authorizes FDA to establish tolerances for unapproved new animal drugs where edible portions of animals imported into the United States may contain residues of such drugs (import tolerances). It is unlawful to import animal-derived food that bears or contains residues of a new animal drug that is not approved in the United States, unless FDA has established an import tolerance for that new animal drug and the residue of the new animal drug in the animal-derived food does not exceed that tolerance.

Timetable:

Action	Date	FR Cite
NPRM	03/00/12	
NPRM Comment Period End	06/00/12	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Thomas Moskal, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, Room 101, (MPN–4, HFV–232), 7519 Standish Place, Rockville, MD 20855

Phone: 240 276–9242

Fax: 240 276–9241

Email: thomas.moskal@fda.hhs.gov

RIN: 0910–AF78

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333. LASER PRODUCTS; AMENDMENT TO PERFORMANCE STANDARD

Legal Authority: 21 USC 360hh to 360ss; 21 USC 371; 21 USC 393

Abstract: FDA is proposing to amend the performance standard for laser products to achieve closer harmonization between the current standard and the International Electrotechnical Commission (IEC) standard for laser products and medical laser products. The proposed amendment is intended to update FDA's performance standard to reflect advancements in technology. The proposal would adopt portions of an IEC standard to achieve greater harmonization and reflect current science. In addition, the proposal would include an alternative mechanism for providing certification and identification, address novelty laser products, and clarify the military exemption for laser products.

Timetable:

Action	Date	FR Cite
NPRM	01/00/12	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Nancy Pirt, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, WO 66, Room 4438, 10903 New Hampshire Avenue, Silver Spring, MD 20993

Phone: 301 796–6248

Fax: 301 847–8145

Email: nancy.pirt@fda.hhs.gov

RIN: 0910–AF87

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334. CURRENT GOOD MANUFACTURING PRACTICE AND HAZARD ANALYSIS AND RISK–BENEFIT PREVENTIVE CONTROLS FOR FOOD FOR ANIMALS

Regulatory Plan: This entry is Seq. No. 34 in part II of this issue of the **Federal Register**.

RIN: 0910–AG10

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335. OVER–THE–COUNTER (OTC) DRUG REVIEW–PEDIATRIC DOSING FOR COUGH/COLD PRODUCTS

Legal Authority: 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action will propose changes to the final monograph to address safety and efficacy issues associated with pediatric cough and cold products.

Timetable:

Action	Date	FR Cite
NPRM	07/00/12	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Mary Chung, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993

Phone: 301 796–0260

Fax: 301 796–9899

Email: mary.chung@fda.hhs.gov

RIN: 0910–AG12

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336. ELECTRONIC DISTRIBUTION OF CONTENT OF LABELING FOR HUMAN PRESCRIPTION DRUG AND BIOLOGICAL PRODUCTS

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 360b; 21 USC 360gg to 360ss; 21 USC 371; 21 USC 374; 21 USC 379e; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 264

Abstract: This rule would require electronic package inserts for human drug and biological prescription products with limited exception, in lieu of paper, which is currently used. These inserts contain prescribing

information intended for healthcare practitioners. This would ensure that the information accompanying the product is the most up-to-date information regarding important safety and efficacy issues about these products.

Timetable:

Action	Date	FR Cite
NPRM	12/00/11	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Megan Clark–Velez, Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Office of Policy, WO Building 32, Room 4249, 10903 New Hampshire Avenue, Silver Spring, MD 20993

Phone: 301 796–9301

Email: megan.clark@fda.hhs.gov

RIN: 0910–AG18

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337. AMENDMENT TO THE CURRENT GOOD MANUFACTURING PRACTICE REGULATIONS FOR FINISHED PHARMACEUTICALS—SECOND PHASE

Legal Authority: 21 USC 321; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 360b; 21 USC 371; 21 USC 374; 42 USC 262; 42 USC 264

Abstract: The Food and Drug Administration (FDA) periodically reassesses and revises the cGMP regulations to accommodate advances in technology and other scientific knowledge that further safeguard the drug manufacturing process and the public health. In August 2002, FDA announced the Pharmaceutical cGMPs for the 21st Century Initiative. As part of the Initiative, FDA created a cGMP Harmonization Analysis Working Group to analyze related cGMP requirements in the United States and internationally. The cGMP working group compared 21 CFR parts 210 and 211 with the cGMPs of the European Union, as well as other FDA regulations (such as the Quality Systems Regulation in 21 CFR part 820) to identify differences and consider the value of supplementing or changing the current regulations. Based on the cGMP Working Group's analysis, FDA decided to take an incremental approach to modifying 21 CFR parts 210 and 211. In September of 2008, FDA published a final rule revising the cGMP regulations primarily in the areas of aseptic processing, use of asbestos filters, and verification of operations by a second individual; this final

rule represented the culmination of the first increment of modifications to the cGMP regulations. The proposed rule identified on this Unified Agenda would begin the second increment of modifications to the cGMP regulations.

Timetable:

Action	Date	FR Cite
NPRM	03/00/12	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: S. Mitchell Weitzman, Regulatory Counsel, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 6318, 10903 New Hampshire Avenue, Silver Spring, MD 20993

Phone: 301 796–3511

Fax: 301 847–8440

Email: smitchell.weitzman@fda.hhs.gov

RIN: 0910–AG20

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338. UNIQUE DEVICE IDENTIFICATION

Regulatory Plan: This entry is Seq. No. 35 in part II of this issue of the **Federal Register**.

RIN: 0910–AG31

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339. PRODUCE SAFETY REGULATION

Regulatory Plan: This entry is Seq. No. 36 in part II of this issue of the **Federal Register**.

RIN: 0910–AG35

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340. HAZARD ANALYSIS AND RISK–BASED PREVENTIVE CONTROLS

Regulatory Plan: This entry is Seq. No. 37 in part II of this issue of the **Federal Register**.

RIN: 0910–AG36

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341. "TOBACCO PRODUCTS" SUBJECT TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, AS AMENDED BY THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

Legal Authority: 21 USC 301 et seq, The Federal Food, Drug, and Cosmetic Act; PL 111–31, The Family Smoking Prevention and Tobacco Control Act

Abstract: The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) provides FDA authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. Section 901 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Tobacco Control Act, permits FDA to issue regulations deeming other tobacco products to be subject to the FD&C Act. This proposed rule would deem products meeting the statutory definition of "tobacco product" found at section 201(rr) of the FD&C Act to be subject to Chapter IX of the FD&C Act and would clarify additional restrictions under the FD&C Act. The scope of the proposed rule deeming cigars that was previously included in the Unified Agenda is being broadened to encompass products that meet the statutory definition of "tobacco product."

Timetable:

Action	Date	FR Cite
NPRM	12/00/11	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: May Nelson, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 9200 Corporate Boulevard, Rockville, MD 20850

Phone: 877 287–1373

Fax: 240 276–3904

Email: may.nelson@fda.hhs.gov

RIN: 0910–AG38

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342. HUMAN SUBJECT PROTECTION; ACCEPTANCE OF DATA FROM CLINICAL STUDIES FOR MEDICAL DEVICES

Legal Authority: Not Yet Determined

Abstract: The Food and Drug Administration (FDA) is proposing to amend its regulations on acceptance of data from clinical studies conducted in support of a premarket approval application, humanitarian device exemption application, an investigational device exemption application, or a premarket notification submission for a medical device.

Timetable:

Action	Date	FR Cite
NPRM	04/00/12	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Sheila Anne Brown, Policy Analyst, Investigational Device Exemptions Staff, Department of Health and Human Services, Food and Drug Administration, WO 66, Room 1651, 10903 New Hampshire Avenue, Silver Spring, MD 20993

Phone: 301 796–6563

Fax: 301 847–8120

Email: sheila.brown@fda.hhs.gov

RIN: 0910–AG48

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343. GENERAL HOSPITAL AND PERSONAL USE DEVICES: ISSUANCE OF DRAFT SPECIAL CONTROLS GUIDANCE FOR INFUSION PUMPS

Legal Authority: 21 USC 351; 21 USC 360; 21 USC 360c; 21 USC 360e; 21 USC 360j; 21 USC 371

Abstract: Since 2003, FDA has seen a dramatic increase in the number of device recalls, as well as an increase in the number of death and serious injury reports submitted regarding infusion pumps. An analysis of the reports reveals that a majority of the recalls and failures were caused by user error and/or device design flaw. As a result of these incidents, FDA is proposing to change the classification of infusion pumps from class II (performance standards) to class II (special controls). Along with the proposed rule, FDA plans to announce a draft special controls guidance document that, when final, will be a special control for infusion pumps. The agency believes that establishing these special controls for infusion pumps is necessary to provide reasonable assurance of the safety and effectiveness of these devices.

Timetable:

Action	Date	FR Cite
NPRM	05/00/12	
NPRM Comment Period End	08/00/12	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Nancy Pirt, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, WO 66 Room 4438, 10903 New Hampshire Avenue, Silver Spring, MD 20993

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RIN: 0910–AG54

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344. REQUIREMENTS FOR THE TESTING AND REPORTING OF TOBACCO PRODUCT CONSTITUENTS, INGREDIENTS, AND ADDITIVES

Legal Authority: PL 111–31, The Family Smoking Prevention and Tobacco Control Act, sec 101(b)

Abstract: Section 915 of the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act, requires FDA to promulgate regulations that require the testing and reporting of tobacco product constituents, ingredients, and additives, including smoke constituents that the agency determines should be tested to protect the public health.

Timetable:

Action	Date	FR Cite
NPRM	08/00/12	
NPRM Comment Period End	10/00/12	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Carol Drew, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Rm 240 H, 9200 Corporate Boulevard, Rockville, MD 20850

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Email: carol.drew@fda.hhs.gov

RIN: 0910–AG59

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345. AMENDMENTS TO THE CURRENT GOOD MANUFACTURING PRACTICE REGULATIONS FOR FINISHED PHARMACEUTICALS—COMPONENTS

Legal Authority: 21 USC 321; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 360b; 21 USC 371; 21 USC 374; 42 USC 262; 42 USC 264

Abstract: This rule proposes to amend regulations regarding the control over components used in manufacturing finished pharmaceuticals.

Timetable:

Action	Date	FR Cite
NPRM	03/00/12	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Brian Hasselbalch, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 4364, 10903 New Hampshire Avenue, Silver Spring, MD 20993

Phone: 301 796–3279

Email: brian.hasselbalch@fda.hhs.gov

Paula Katz, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 1320, 10903 New Hampshire Avenue, Silver Spring, MD 20993

Phone: 301 796–6972

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RIN: 0910–AG70

Department of Health and Human Services (HHS)	Final Rule Stage
Food and Drug Administration (FDA)	

346. INFANT FORMULA: CURRENT GOOD MANUFACTURING PRACTICES; QUALITY CONTROL PROCEDURES; NOTIFICATION REQUIREMENTS; RECORDS AND REPORTS; AND QUALITY FACTORS

Regulatory Plan: This entry is Seq. No. 40 in part II of this issue of the **Federal Register**.

RIN: 0910–AF27

347. LABEL REQUIREMENT FOR FOOD THAT HAS BEEN REFUSED ADMISSION INTO THE UNITED STATES

Legal Authority: 15 USC 1453 to 1455; 21 USC 321; 21 USC 342 and 343; 21 USC 371; 21 USC 374; 21 USC 381; 42 USC 216; 42 USC 264

Abstract: The final rule will require owners or consignees to label imported food that is refused entry into the United States. The label will read, “UNITED STATES: REFUSED ENTRY.” The proposal describes the label's characteristics (such as its size) and processes for verifying that the label has been affixed properly. We are taking this action to prevent the introduction of unsafe food into the United States, to facilitate the examination of imported food, and to implement section 308 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Pub. L. 107-188).

Timetable:

Action	Date	FR Cite
NPRM	09/18/08	73 FR 54106
NPRM Comment Period End	12/02/08	
Final Action	06/00/12	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Daniel Sigelman, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, WO Building 32, Room 4254, 10903 New Hampshire Avenue, Silver Spring, MD 20993

Phone: 301 796–4706

Email: daniel.sigelman@fda.hhs.gov

RIN: 0910–AF61

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348. FOOD LABELING: NUTRITION LABELING FOR FOOD SOLD IN VENDING MACHINES

Regulatory Plan: This entry is Seq. No. 43 in part II of this issue of the **Federal Register**.

RIN: 0910–AG56

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349. FOOD LABELING: NUTRITION LABELING OF STANDARD MENU ITEMS IN RESTAURANTS AND SIMILAR RETAIL FOOD ESTABLISHMENTS

Regulatory Plan: This entry is Seq. No. 44 in part II of this issue of the **Federal Register**.

RIN: 0910–AG57

Department of Health and Human Services (HHS)	**Long-Term Actions**
Food and Drug Administration (FDA)	

350. FOOD LABELING; REVISION OF THE NUTRITION AND SUPPLEMENT FACTS LABELS

Legal Authority: 21 USC 321; 21 USC 343; 21 USC 371

Abstract: In the Federal Register of July 11, 2003 (68 FR 41507), FDA published an ANPRM (the 2003 ANPRM) to solicit information and data on trans fat labeling and claims made about trans fats. Comments received to the 2003 ANPRM that pertain to the labeling of trans fat will be addressed in this proposed rule. In addition, the Agency published an ANPRM on the prominence of calories on the food label on April 4, 2005 (the 2005 ANPRM) (70 FR 17008), and an ANPRM on the revision of reference values and mandatory nutrients on November 2, 2007 (the 2007 ANPRM) (72 FR 62149). The Agency also intends to address the comments received to the 2005 and 2007 ANPRM's in this proposed rule.

FDA is proposing to amend labeling regulations for conventional foods and dietary supplements to provide updated nutrition information on the label to assist consumers in maintaining healthy dietary practices. Mandatory nutrition labeling of food was first required in 1993. Much of the information found on the Nutrition Facts label has not been updated since that time. If finalized, this rule will modernize the nutrition information found on the Nutrition Facts label, as well as the format and appearance of the label.

Among the changes proposed, the Agency intends to: 1) Provide updated Daily Reference values (DRVs) and Reference Daily Intake values (RDIs) that are based on the latest scientific evidence from consensus reports, such as the Institute of Medicine Dietary Reference Intakes; 2) provide DRVs and RDIs, as well as requirements for foods purported to be for children under 4 years of age and pregnant or lactating women; and 3) make changes to the mandatory declaration of specific nutrients. The Agency is also considering

revisions to the format and appearance of the Nutrition Facts label and the Supplement Facts label, including the prominence of calories on the label.

Timetable:

Action	Date	FR Cite
ANPRM	07/11/03	68 FR 41507
ANPRM Comment Period End	10/09/03	
ANPRM	04/04/05	70 FR 17008
ANPRM Comment Period End	06/20/05	
ANPRM	11/02/07	72 FR 62149
ANPRM Comment Period End	01/31/08	
NPRM	12/00/12	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Blakeley Fitzpatrick, Interdisciplinary Scientist, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS–830), HFS–830, 5100 Paint Branch Parkway, College Park, MD 20740

Phone: 240 402–1450

Email: blakeley.fitzpatrick@fda.hhs.gov

RIN: 0910–AF22

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351. OVER–THE–COUNTER (OTC) DRUG REVIEW—ORAL HEALTH CARE PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360 to 360a; 21 USC 371 to 371a

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be

legally marketed. The NPRM and final action will address oral health care products used to reduce or prevent dental plaque and gingivitis.

Timetable:

Action	Date	FR Cite
ANPRM (Plaque Gingivitis)	05/29/03	68 FR 32232
ANPRM Comment Period End	08/27/03	
NPRM (Benzocaine)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: David Eng, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5487, 10903 New Hampshire Avenue, Silver Spring, MD 20993

Phone: 301 796–2773

Fax: 301 796–9899

Email: david.eng@fda.hhs.gov

RIN: 0910–AF40

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352. PET FOOD LABELING REQUIREMENTS

Legal Authority: 21 USC 343; 21 USC 371; PL 110–85, sec 1002(a)(3)

Abstract: The President signed into law the Food and Drug Administration Amendments Act of 2007 (FDAAA) on September 27, 2007 (Pub. L. 110-85). Title X of the FDAAA includes several provisions pertaining to food safety, including the safety of pet food. Section 1002(a)(3) of the new law directs FDA to issue new regulations to establish updated standards for the labeling of pet food that include nutritional and ingredient information. This same provision of the law also directs that, in developing these new regulations, FDA consult with the Association of American Feed Control Officials and other relevant stakeholder groups, including veterinary medical associations, animal health organizations, and pet food manufacturers.

Timetable:

Action	Date	FR Cite

NPRM	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: William Burkholder, Veterinary Medical Officer, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, Room 2642 (MPN–4, HFV–228), 7519 Standish Place, Rockville, MD 20855

Phone: 240 453–6865

Email: william.burkholder@fda.hhs.gov

RIN: 0910–AG09

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353. FURTHER AMENDMENTS TO GENERAL REGULATIONS OF THE FOOD AND DRUG ADMINISTRATION TO INCORPORATE TOBACCO PRODUCTS

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 333; 21 USC 371; 21 USC 381; 21 USC 387; 21 USC 387a; 21 USC 387c; 21 USC 387f; 21 USC 387k; 15 USC 1333; 15 USC 4402

Abstract: The Food and Drug Administration is seeking to amend certain of its general regulations to include tobacco products, where appropriate, in light of FDA's authority to regulate these products under the Family Smoking Prevention and Tobacco Control Act. The final rule will cover revisions to the document reporting requirements and definition of “product.”

Timetable:

Action	Date	FR Cite
NPRM	04/14/11	76 FR 20901
NPRM Comment Period End	06/13/11	
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Gerie Voss, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 9200 Corporate Boulevard, Rockville, MD 20850

Phone: 877 287–1373

Fax: 240 276–4193

Email: gerie.voss@fda.hhs.gov

RIN: 0910–AG60

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354. • FOOD LABELING: HARD CANDIES AND BREATH MINTS

Legal Authority: 21 USC 321; 21 USC 343; 21 USC 371

Abstract: The Food and Drug Administration is proposing to amend certain provisions of its serving size regulations to change the label serving size for breath mints to one unit. This action is in response to an advanced notice of proposed rulemaking published in 2005, in which FDA requested comment on whether to amend certain provisions of its nutrition labeling regulations concerning serving size and a 1997 proposed rule entitled Food Labeling: Hard Candies and Breath Mints (62 FR 67775).

Timetable:

Action	Date	FR Cite
NPRM	12/30/97	62 FR 67775
NPRM Comment Period End	03/16/98	
ANPRM	04/05/05	70 FR 17010
ANPRM Comment Period End	06/20/05	
NPRM	12/00/12	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Mark Kantor, Nutritionist, Department of Health and Human Services, Food and Drug Administration, 5100 Paint Branch Parkway, HFS–830, College Park, MD 20740

Phone: 240 402–1450

Fax: 301 436–1191

Email: mark.kantor@fda.hhs.gov

RIN: 0910–AG82

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355. • FOOD LABELING; SERVING SIZES; REFERENCE AMOUNTS FOR CANDIES

Legal Authority: 21 USC 321; 21 USC 343; 21 USC 371

Abstract: The Food and Drug Administration is proposing to amend certain provisions of its serving size regulations to provide updated Reference Amounts Customarily Consumed for candies. This action is in

response to an advance notice of proposed rulemaking published in 2005, in which FDA requested comment on whether to amend certain provisions of its nutrition labeling regulations concerning serving size and a 1998 proposed rule entitled “Food Labeling: Reference Amounts for Candies” (63 FR 1078).

Timetable:

Action	Date	FR Cite
NPRM	01/08/98	63 FR 1078
NPRM Comment Period End	02/09/98	
ANPRM	04/05/05	70 FR 17010
ANPRM Comment Period End	06/20/05	
NPRM	12/00/12	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Mark Kantor, Nutritionist, Department of Health and Human Services, Food and Drug Administration, 5100 Paint Branch Parkway, HFS–830, College Park, MD 20740

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RIN: 0910–AG83

Department of Health and Human Services (HHS)	Completed Actions
Food and Drug Administration (FDA)	

356. OVER–THE–COUNTER (OTC) DRUG REVIEW—COUGH/COLD (BRONCHODILATOR) PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only

OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses labeling for single ingredient bronchodilator products.

Timetable:

Action	Date	FR Cite
NPRM (Amendment—Ephedrine Single Ingredient)	07/13/05	70 FR 40237
NPRM Comment Period End	11/10/05	
Final Action (Technical Amendment)	11/30/07	72 FR 67639
Final Action (Amendment—Single Ingredient Labeling)	07/26/11	76 FR 44475

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Mary Chung, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993

Phone: 301 796–0260

Fax: 301 796–9899

Email: mary.chung@fda.hhs.gov

RIN: 0910–AF32

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357. OVER–THE–COUNTER (OTC) DRUG REVIEW—POISON TREATMENT DRUG PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses the ingredient ipecac syrup.

Timetable:

Action	Date	FR Cite

Withdrawn	09/08/11	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: David Eng, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5487, 10903 New Hampshire Avenue, Silver Spring, MD 20993

Phone: 301 796–2773

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Email: david.eng@fda.hhs.gov

RIN: 0910–AF68

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358. CIGARETTE WARNING LABEL STATEMENTS

Legal Authority: PL 111–31, The Family Smoking Prevention and Tobacco Control Act, sec 201

Abstract: Section 4 of the FCLAA, as amended by section 201 of the Tobacco Control Act, requires FDA to issue regulations that require color graphics depicting the negative health consequences of smoking to accompany required warning statements on cigarette packages and advertisements. FDA also may adjust the type size, text and format of the required label statements on product packaging and advertising if FDA determines that it is appropriate so that both the graphics and the accompanying label statements are clear, conspicuous, legible and appear within the specified area.

Timetable:

Action	Date	FR Cite
NPRM	11/12/10	75 FR 69524
NPRM Comment Period End	01/11/11	
Final Action	06/22/11	76 FR 36628

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Gerie Voss, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 9200 Corporate Boulevard, Rockville, MD 20850

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RIN: 0910–AG41

Department of Health and Human Services (HHS)	Proposed Rule Stage
Centers for Medicare & Medicaid Services (CMS)	

359. COVERED OUTPATIENT DRUGS (CMS–2345–P) (SECTION 610 REVIEW)

Legal Authority: PL 111– 48, secs 2501 and 2503

Abstract: This proposed rule would revise requirements pertaining to Medicaid reimbursement for covered outpatient drugs to implement provisions of the Affordable Care Act. This proposed rule would also revise other requirements related to covered outpatient drugs, including key aspects of Medicaid coverage, payment, and the drug rebate program.

Timetable:

Action	Date	FR Cite
NPRM	01/00/12	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Wendy Tuttle, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations, Mail Stop S2–14–26, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–8690

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RIN: 0938–AQ41

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360. MEDICARE AND MEDICAID ELECTRONIC HEALTH RECORD INCENTIVE PROGRAM—STAGE 2 (CMS–0044–P)

Legal Authority: PL 111–5 secs 4101, 4102, and 4202

Abstract: The final rule for the Medicare and Medicaid EHR Incentive Programs, which was published in the Federal Register on July 28, 2010, specifies that CMS will expand on the criteria for meaningful use

established for Stage 1 to advance the use of certified EHR technology by eligible professionals (EPs), eligible hospitals and critical access hospitals (CAHs). This proposed rule would establish the requirements for Stage 2. As stated in the July 28 final rule, "Our goals for the Stage 2 meaningful use criteria, consistent with other provisions of Medicare and Medicaid law, expand upon the Stage 1 criteria to encourage the use of health IT for continuous quality improvement at the point of care and the exchange of information in the most structured format possible, such as the electronic transmission of orders entered using computerized provider order entry (CPOE) and the electronic transmission of diagnostic test results."

Timetable:

Action	Date	FR Cite
NPRM	02/00/12	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Elizabeth Holland, Director, Health Initiatives Group/Office of e–Health Standards and Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop S2–26–17, 7500 Security Boulevard, Baltimore, MD 21244

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Email: elizabeth.holland@cms.hhs.gov

RIN: 0938–AQ84

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361. MEDICARE AND MEDICAID PROGRAMS: REFORM OF HOSPITAL AND CRITICAL ACCESS HOSPITAL CONDITIONS OF PARTICIPATION (CMS–3244–P)

Regulatory Plan: This entry is Seq. No. 45 in part II of this issue of the **Federal Register**.

RIN: 0938–AQ89

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362. • PROPOSED CHANGES TO HOSPITAL OPPS AND CY 2013 PAYMENT RATES; ASC PAYMENT SYSTEM AND CY 2013 PAYMENT RATES (CMS–1589–P) (SECTION 610 REVIEW)

Regulatory Plan: This entry is Seq. No. 47 in part II of this issue of the **Federal Register**.

RIN: 0938–AR10

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363. • REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE AND PART B FOR CY 2013 (CMS–1590–P) (SECTION 610 REVIEW)

Regulatory Plan: This entry is Seq. No. 48 in part II of this issue of the **Federal Register**.

RIN: 0938–AR11

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364. • CHANGES TO THE HOSPITAL INPATIENT AN LONG–TERM CARE PROSPECTIVE PAYMENT SYSTEM FOR FY 2013 (CMS–1588–P) (SECTION 610 REVIEW)

Regulatory Plan: This entry is Seq. No. 49 in part II of this issue of the **Federal Register**.

RIN: 0938–AR12

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365. • TRANSPARENCY REPORTS AND REPORTING OF PHYSICIAN OWNERSHIP OF INVESTMENT INTERESTS (CMS–5060–F)

Legal Authority: PL 111–148, sec 6002

Abstract: This final rule requires applicable manufacturers of drugs, devices, biologicals, or medical supplies covered by Medicare, Medicaid, or CHIP to report annually to the Secretary certain payments or transfers of value provided to physicians or teaching hospitals (“covered recipients”). In addition, applicable manufacturers and applicable group purchasing organizations (GPOs) are required to report annually certain physician ownership or investment interests. The Secretary is required to publish applicable manufacturers’ and applicable GPOs’ submitted payment and ownership information on a public website.

Timetable:

Action	Date	FR Cite
NPRM	12/19/11	76 FR 78742
NPRM Comment Period End	02/17/12	
Final Action	12/00/14	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Niall Brennan, Director, Policy and Data Analysis Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Blvd,, Baltimore,, MD 21244

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RIN: 0938–AR33

Department of Health and Human Services (HHS)	Completed Actions
Centers for Medicare & Medicaid Services (CMS)	

366. PROPOSED CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS FOR ACUTE CARE HOSPITALS AND FY 2012 RATES AND TO THE LONG–TERM CARE HOSPITAL PPS AND FY 2012 RATES (CMS–1518–F) (COMPLETION OF A SECTION 610 REVIEW)

Legal Authority: sec 1886(d) of the Social Security Act; PL 111–148 secs 3004, 3025

Abstract: This rule revises the Medicare hospital inpatient and long-term care hospital prospective payment systems for operating and capital-related costs. This rule implements changes arising from our continuing experience with these systems.

Timetable:

Action	Date	FR Cite
NPRM	05/05/11	76 FR 25788
NPRM Comment Period End	06/20/11	
Final Action	08/18/11	76 FR 51476

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Ankit Patel, Health Insurance Specialist, Division of Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Hospital and Ambulatory Policy Group, Mail Stop, C4–25–11, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–4537

Email: ankit.patel@cms.hhs.gov

RIN: 0938–AQ24

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367. REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE AND PART B FOR CY 2012 (CMS–1524–FC) (COMPLETION OF A SECTION 610 REVIEW)

Legal Authority: Social Security Act, sec 1102; Social Security Act, sec 1871; PL 111–148

Abstract: This annual rule revises payment polices under the physician fee schedule, as well as other policy changes to payment under Part B. These changes are be applicable to services furnished on or after January 1.

Timetable:

Action	Date	FR Cite
NPRM	07/19/11	76 FR 42772
NPRM Comment Period End	08/30/11	
Final Action	11/28/11	76 FR 73026
Final Action Effective	01/01/12	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Christina Ritter, Director, Division of Practitioner Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop C4–03–06, 7500 Security Boulevard, Baltimore, MD 21244

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RIN: 0938–AQ25

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368. CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEM FOR CY 2012 (CMS–1525–F) (COMPLETION OF A SECTION 610 REVIEW)

Legal Authority: Social Security Act, sec 1833; PL 111–148 sec 6001

Abstract: This rule revises the Medicare hospital outpatient prospective payment system to implement applicable statutory requirements and changes arising from our continuing experience with this system. The proposed rule also describes changes to the amounts and factors used to determine payment rates for services. In addition, the rule finalizes changes to the Ambulatory Surgical Center Payment System list of services and rates.

Timetable:

Action	Date	FR Cite

NPRM	07/18/11	76 FR 42170
NPRM Comment Period End	08/30/11	
Final Action	11/30/11	76 FR 74122

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AQ26

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369. PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING FOR SKILLED NURSING FACILITIES FOR FY 2012; REQUIRED DISCLOSURES OF OWNERSHIP (CMS–1351–F) (COMPLETION OF A SECTION 610 REVIEW)

Legal Authority: Social Security Act, sec 1888(e), PL 111–148, sec 6101

Abstract: This major rule finalizes two options for updating the payment rates used under the prospective payment system (SNFs), for fiscal year 2012. In this context, it examines recent changes in provider behavior relating to the implementation of the Resource Utilization Groups, version 4 (RUG-IV) case-mix classification system, discusses how such changes may affect the objective of maintaining parity in overall expenditures between RUG-IV and the previous case-mix classification system, and considers a possible recalibration of the case-mix indexes so that they more accurately reflect parity in expenditures. It also includes a discussion of a Non-Therapy Ancillary component and outlier research currently under development within CMS. In addition, this rule discusses the impact of certain provisions of the Affordable Care Act , and new programs and initiatives affecting SNFs. It also implements section 3401(b) of the Affordable Care Act, which requires for fiscal year 2012 and subsequent fiscal years that the SNF market basket percentage change be reduced by the multi-factor productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. It also implements section 6101 of the Affordable Care Act, which requires

Medicare SNFs and Medicaid nursing facilities to disclose certain information to the Secretary and other entities regarding the ownership and organizational structure of their facilities.

Timetable:

Action	Date	FR Cite
NPRM	05/06/11	76 FR 26364
NPRM Comment Period End	06/27/11	
Final Action	08/08/11	76 FR 48486

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AQ29

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370. HOME HEALTH PROSPECTIVE PAYMENT SYSTEM REFINEMENTS AND RATE UPDATE FOR CY 2012 (CMS–1353–F) (SECTION 610 REVIEW)

Legal Authority: Social Security Act, secs 1102 and 1871; 42 USC 1302 and 1395(hh); Social Security Act, sec 1895; 42 USC 1395(fff), PL 111–148 secs 3131, 3401, 6407

Abstract: This rule updates the 60-day national episode rate (based on the applicable Home Health Market Basket Update and case-mix adjustment) and would also update the national per-visit rates (used to calculate low utilization payment adjustments (LUPAs) and outlier payments) amounts under the Medicare Prospective Payment System for home health agencies. These changes are applicable to services furnished on or after January 1st.

Timetable:

Action	Date	FR Cite
NPRM	07/12/11	76 FR 40988

NPRM Comment Period End	09/06/11	
Final Action	11/04/11	76 FR 68526

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AQ30

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371. ENHANCED FEDERAL FUNDING FOR MEDICAID ELIGIBILITY DETERMINATION AND ENROLLMENT ACTIVITIES (CMS–2346–F)

Legal Authority: PL 111–148, sec 1413

Abstract: The Affordable Care Act requires States' residents to apply, enroll, receive determinations, and participate in the State health subsidy programs known as "the Exchange". The Affordable Care Act requires many changes to State eligibility and enrollment systems and each State is responsible for developing a secure, electronic interface allowing the exchange of data. Existing legacy eligibility systems are not able to implement the numerous requirements. This rule is key to informing States about the higher rates that CMS will provide to help them update or build legacy eligibility systems that meet the ACA requirements.

Timetable:

Action	Date	FR Cite
NPRM	11/08/10	75 FR 68583
NPRM Comment Period End	01/07/11	
Final Action	04/19/11	76 FR 21950

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AQ53

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372. FIVE YEAR REVIEW OF WORK RELATIVE VALUE UNITS UNDER THE PHYSICIAN FEE SCHEDULE (CMS–1582–PN)

Legal Authority: SSA, sec 1848(c)(2)(B)(i)

Abstract: This proposed notice sets forth proposed revisions to work relative value units (RVUs) affecting payment for physicians' services. The Act requires that we review RVUs no less than every five years. The revised values will be finalized in the CY 2012 Physician Fee Schedule final rule and will be effective for services furnished beginning January 1, 2012.

Timetable:

Action	Date	FR Cite
Notice	06/06/11	76 FR 32410
Merged With 0938–AQ25	07/07/11	

Regulatory Flexibility Analysis Required: Yes

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